The Relationship Between Politics, Economics, the Precautionary Principle and Bradford Hill's Criteria for Cause and Effect.

When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships, e.g., the Criteria for Causation, are not fully established scientifically. For years, the environmental and public health movements have been struggling to find ways to protect health and the environment in the face of scientific uncertainty about cause and effect. The public has typically carried the burden and cost of proving that a particular activity or substance is dangerous, while those undertaking potentially dangerous activities and the products of those activities are considered innocent until proven guilty. Chemicals, released pathogens, including dangerous practices, and those that produce them often seem to have more rights than citizens and the environment.

This burden of scientific proof has posed a monumental barrier in the campaign to protect health and the environment. Actions to prevent harm are usually taken only after significant proof of harm is established, at which point it may be too late. As Gerba notes in one of his papers--***"Man has continually polluted his environment with his waste products. Only recently has he been strongly confronted with the consequences...."***

Hazards are generally addressed by industry and government agencies one at a time, in terms of a single mal-actor, rather than as broader issues such as the need to promote public health. When citizen groups base their calls for a stop to a particular activity on experience, observation, or anything less than stringent scientific proof, they are accused of being emotional and hysterical and the data are termed anecdotal.

To overcome this barrier, advocates need a decision-making and action tool with ethical power and scientific rigor. The precautionary principle, which has become a critical aspect of environmental agreements and environmental activism throughout the world, offers the public and decision-makers a forceful, common-sense approach to environmental and public health problems.

Admittedly, of the debate over the depth and breadth of water pollution [including sanitation], a considerable portion is beset by uncertainty. The uncertainty accrues to a range of opinion on causation as well as effect. For example, the questions may range from ones of how extensive or important the damage might be to questions asking if the issue indeed has any merit at all.

Thus, within this area of uncertainty, at least five major sources might concern those working in the field. The first is that of the need to measure the extents in degradation. Secondly, this then requires that there be an ability to differentiate human effect from ongoing natural processes. Thirdly, to determine if such

and those charged with the Public Trust to be willing to blend the Precautionary Principles and the Bradford Hill Criteria.

The United States Supreme Court in it's Daubert's decision, addressed that issue and concluded that the expert has to provide scientific opinion, based on methods and techniques generally used, and/or **relying on peer reviewed publications** for testability of his opinion that causation is more likely than not due to the item under consideration or in question (51% probability).

The expert does not necessarily need to rely on epidemiology, or scientific certainty "or provide scientific proof", but rather follow the below quoted guidelines applied in the U.S. Supreme Court Daubert decision. The expert should know the accepted methodology to establish causation described in the scientific and medical literature, and established originally by Sir Bradford-Hill.

These criteria are the cornerstone of establishing causation, and are described as follows:

CONSISTENCY AND UNBIASEDNESS OF FINDINGS

Confirmation of the association by different investigators, in different populations, using different methods.

In the case of Cottage Hospital and issues of released sewage, there are several peer reviewed papers (national and international) that indicate hospital effluent is not only different than that derived from the community, but often carries detrimental materials and serious pathogens that are not effectively cleared from sewage prior to release to the environment. Taking this body of literature together, and also applying the above Precautionary Principle should both alert contentious public servants and the decision-making arms of government that there is an issue warranting correction.

STRENGTH OF ASSOCIATION

Two aspects: the frequency with which the factor is found associated with the problem, and the frequency with which it occurs in the absence of the problem. The larger the relative risk, the more the hypothesis is strengthened.

In the case of multi-drug resistance, there is an increasing association with hospitals. Additionally, there is now a growing level of community acquired resistance within pathogens. The issue is one of suggesting that hospitals are foci of drug resistance. There are sufficient data within the literature to suggest this, thus the Precautionary Principle comes into play here. Again, several papers have demonstrated failure of current water quality standards to adequately protect public health. Further, sufficiency within the literature demonstrates that wastewater plants are unable to effectively clear both pathogens and materials that augment resistance or virulence. Thus, removing resistant pathogens and materials that augment such, would likely see a drop in the level and rate of gained resistance. This has been demonstrated in Europe and several peer-reviewed papers are available.

TEMPORAL SEQUENCE

Obviously, exposure to the factor must occur before onset of the increased risk. In addition, it is possible to show both spatial and temporal relationships between exposure to the factor in the environment. Again, these factors are well demonstrated within the literature accompanying this commentary submittal.

BIOLOGICAL GRADIENT (DOSE-RESPONSE RELATIONSHIP)

Finding a quantitative relationship between the factor and the frequency of the disease. The intensity or duration of exposure may be measured. In the case of augmenting selection, there is a dose response relationship between exposure of microbes to materials that select for resistance. There is also a positive relationship between sewage plants and the augmentation of resistance as seen between influents and the release of effluents. Hospitals and their sewage effluents have been shown to contribute to this more than urban effluents. Again---see accompanying literature.

SPECIFICITY

If the determinant being studied can be isolated from others and shown to produce changes in the incidence of the problem, e.g., if drug-resistance can be shown to have a higher incidence of morbidity and mortality, this is convincing evidence of causation. If hospitals can be shown to produce and release via their sewage, higher levels and more resistant pathogens, then this is also convincing evidence. In both cases, data are abundant and attached.

COHERENCE WITH BIOLOGICAL BACKGROUND AND PREVIOUS KNOWLEDGE

The evidence must fit the facts that are thought to be related, e.g., the rising incidence of resistance and the increasing failure to adequately sequester pathogens are coherent.

BIOLOGICAL PLAUSABILITY

The statistically significant association fits well with previously existing knowledge.

REASONING BY ANALOGY

EXPERIMENTAL EVIDENCE

This aspect focuses on what happens when the suspected offending agent is removed. Is there general overall improvement ? The evidence of reduced levels of resistance follow removal of both antimicrobials and resistant pathogens. The literature is available to demonstrate this.

None of these criteria is perfect, but they give a useful guideline. As Sir Austin Bradford Hill himself notes:

> ***"All scientific work is incomplete- whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. This does not confer upon one a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time. Who knows, asked Robert Browning, but that the world may end to-night? True, but on available evidence most of us make ready to commute on the 8.30 next day."***

differentiation between anthropomorphic versus natural causation is important. And, next, if there is deterioration, then there is much debate over the variety of ways such deterioration can be viewed and, further if there is then a need to mitigate and finally, how. Ultimately, it comes down to considerations related to the different approaches. What is viewed, what is important, what may be ignored, and the-who-and-how of interpreting the variety of data. However, when it comes to risks to public health, the situation warrants considerably more attention.

I would argue that water pollution has been treated as a political-economic issue, and any discussion and ultimate result will therefore rest upon partisan decisions. This is unfortunate and we as a society can no longer tolerate this approach.

Pollution, however, may continue but remain unrecognized or be unimportant to those living in an affected area, i.e., the stakeholder. It only reaches a social issue when deterioration becomes: 1) recognized and 2) some level of action is required. However, until that level of action brings about conflict, pollution has typically not become a problem.

When the issue generates conflict, it may be expressed either politically—**or it may remain unnoticed as merely the over subscription of alternative scarce resources or the overuse of their absorptive capacities.** These latter aspects have been the ongoing status quo here in Santa Barbara.

Unfortunately, so deeply ingrained are the traditional views of humans, which lead to pollution, or its mitigation, that any intervention brings about contradictions within society. Intervention thus implies a mediation or an arising of conditional pressures, especially as regulation shifts from prescriptions to proscription of behavior. An intervention may affect any or all of the following: a) the livelihood of users, b) changes in the allocation of yet other scarce resources, c) changes of the law, or d) rearrangement of pricing structures.

Cause and Effect

Sir Bradford Hill's criteria for causation were developed for the field of occupational medicine, but have been widely applied in other fields. These criteria are meant to serve as a **general guide, and are not meant to be an inflexible list.**

Not all criteria must be fulfilled to establish scientific causation. The key criteria required to establish causation are commonly 1) temporal relationship, 2) specificity, 3) biological plausibility, 4) coherence.

In many instances, defendants will use the tactics of, "there are no epidemiological studies", or, "there is no statistical evidence to show causation for a certain event". Thus, here it becomes critical for public decision-makers

The documents included within this submission and the comments on the Cottage DEIR, stem from a desire to assure the best possible background data upon which to judge the DEIR. Also there is the goal of assisting in and assuring the best possible analysis of impacts, which would consequently assure the best final project.

A project of the magnitude that Cottage envisions will occur perhaps once within the remainder of this century, certainly not more than once within the remainder of my life-time. While it is difficult to predict the future, certain trends are evident. Health care will be increasingly technologically driven. Patients will be seeing clinicians that, by the crush of increased demand for their services and shortness of their supply, will find that these clinicians will no longer have that long-term perspective once attributed to the old family physician. This lack of historical perspective, shortness of patient contact, and reliance on technology, may see missed diagnoses, inappropriate treatment and intervention, as well as hurried decisions.

CC-17

Then there is the current rising specter of antimicrobial resistance, pollution's impact on the environment, hence human health and assaults on the immune system. These will confound diagnoses. The empirical judgement, once a reliable process for prescribing antibiotics, is increasingly failing. This failure accrues to the growing mobility of patients and microbes, both of which are showing increased levels of resistance; the former often unwittingly colonized, the latter carrying new genetic information. Thus, new genetic information conferring both increased resistance and virulence accompanies the microbes that affect this dynamic society. The result is seen in increasing failure of prescribed antibiotics, the consequent morbidity and mortality, and rising health care and community costs.

Some of these potential impacts can be mitigated by careful planning. Of critical importance is that of antimicrobial resistance amongst pathogens and the growing transfer of resistance within the organisms that are now only potential pathogens or within their human carriers. A critical part of this situation and potentially an answer, arises directly from hospitals themselves.

Hospital wastewater is loaded with not only resistant pathogens, but also carries with it materials that augment selection for further resistance. This wastewater enters sewer works that, under current designs and standards, are unable to "treat" this waste. The pathogens and other organisms entrained within this fluid are brought together and are essentially provided a "trades-fair" in which to swap information. The levels of resistance and virulence are often increased by this mixing and brief confinement. The product is then released to the environment as either wastewater or sewer sludge. In either case, these byproducts can adversely impact the environment, setting up serious potential health risks.

To mitigate this eventuality, more analyses are warranted on the sewage impacts and sewage treatment mechanisms. However, such analyses have been excluded form the DEIR. Such analyses should take a Prato-optimal approach. The analyses within the current DEIR has, thus far, failed to take such an approach and has also failed to present itself as a full disclosure document under CEQA. Thus, both the public and decision-makers are deprived of the necessary information with which to adequately judge and navigate the project to a timely and logical conclusion. CC-17

It is with these thoughts in mind that this work is presented. It is hoped, since we have essentially lost an entire year by neglecting this subject, that the data within this submittal will help accelerate the analysis of this critical subject area.

Submitted with all due respect,

Dr. Edward McGowan

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There are several questions that arise from a reading of the DEIR. These can be summarized as follows: CC-18

1. What is the legal basis of utilizing the original Initial Study and the RFP as a basis for the setting of conditions for the EIR? The Initial Study called out the sewage issues as less than significant based on early information of

non-experts. This was later changed to a potentially significant adverse impact by the Planning Commission (PC), who also advised the staff to utilize community expertise in defining the scope of the overall issues. This directive from the PC was obviously ignored, thus, what is the legal basis for ignoring such directives? Please explain how this ignored information and mechanisms allowing for such will be brought before the public and decision-makers for full disclosure. CC-18

2. Ignoring the directives of the PC related to the sewage issues and using the original Initial Study saw premature release of environmental indicators. With the early release of the Initial Study (IS) and RFP (both were submitted to potential consultants around Oct 17, 2003, fully 2 weeks before close of comment), how could consultants properly assess the work? Nonetheless, knowing this shortcoming, the contract for LAS and the City specifies that the work will be based on this earlier submitted data (IS & RFP). What is the legal basis for this posture? By taking this posture, the sewage issue that had been raised to a potentially significant adverse impact was reverted to less than significant---is that legal and can you explain this maneuver within a legal framework? If so, please do. What do you propose to rectify this situation to produce a full disclosure document? CC-19

3. The consultant JPR, per Appendix F of the DEIR, stated that: a) it did not do a peer review of submitted public comments, b) that in essence it was not expert to do so, and thus recommended that expert advice be implemented in pursuit of this, c) there has been no reported expert review presented within the DEIR thus allowing for public review within the comment period of 45 days now running out, c) nonetheless, Consultant JPR proffed conclusions that became critical parts of the baseline upon which the DEIR was based. Thus, the conclusions are suspect and non validated. Additionally, an abundance of published peer reviewed scientific and medical literature (presented during the scoping), refute the JPR consultants conclusions but were ignored and essentially excluded from the DEIR. What is the legal basis to justify such actions? How will later analyses of public comment by expert review be handled and what is the legal basis for with-holding such from the current public review period, if such analyses exist? CC-20

4. Alternative 4B, discussing the expansion of Goleta Valley Hospital (an expansion to almost twice the licensed bed size) fails the alleged test that mere reduction in licensed bed count obviated discussion and impact from CC-21

sewage issues for the main campus in Santa Barbara. What is the legal basis for failing to discuss sewage impacts where there was an anticipated and obvious expansion? Please explain how steps will be taken to rectify this situation and bring this information before the public and decision-makers in full disclosure. There are several issues involved within this subject that include impacts to water resources and quality impacts to fresh and marine receiving waters, public health, permits related to sewer plants, to name a few examples. CC-21

5. During the scoping session and as submitted during public hearing on October 30, 2003, critical issues relating to carpeting and its capacity to be a foci for pathogens was brought to the attention of the City and PC. It appears that this subject has been neglected within the DEIR. Please explain how and under what legal basis this occurred? Please explain what steps will be taken to analyze this subject and bring it before the public and decision-makers in full disclosure. CC-22

6. During the scoping session and as submitted during the public hearing on October 30, 2003, the subject of terrorism was brought up, indicating that within the Santa Barbara core, with the closure of St Francis, Cottage was the only hospital, thus extra ordinary steps should be taken to assure that it was as well designed as possible. This included extra precautions for preclusion of toxic clouds and emergency water deficits. Submitted data demonstrated serious and critical vulnerability in both of these areas, as noted again within the body of this submittal. It appears that these issues have been neglected within the DEIR. Please explain how and under what legal basis this occurred. Please explain how steps will be taken to rectify this situation, analyze these issues, and bring the results before the public and decision-makers in full disclosure. CC-23

7. The DEIR appears to incorporate the expansion project as well as the specific plan (SP-8). Within SP-8, is mention of a 100 bed nursing pavilion. Little information is carried back to tables on beds within the hospital's projected new total bed count. The DEIR also indicates that no adverse impacts will accrue to sewage secondary to a reduction of licensed beds. No CEQA discussion accompanies this conclusionary decision allowing bed reductions to validate the non impact. What is the legal basis for this stance? CC-24

8. Current census is noted to be approximately 213 to 226 occupied beds. Under the new project, the number of licensed beds is projected to be 337. CC-25

The estimated utilization of these 337 beds is projected to be 70%. Thus the projected average census would amount to 236 occupied beds, 10 more than the current upper census number. The DEIR indicates that current bed usage is about 52%. Thus 456 licensed beds at 52% is 237 beds. There is essentially no difference between current and projected census (236 vs 237). The Cottage administration and the DEIR indicate that the licensed figure of 456 beds could never be realized for a variety of technical, policy, and regulatory reasons and the current and long-standing census is 213. Add now the 100 bed nursing pavilion and the projected added increase in out-patients of 22,000. From the above data and prospective, please explain how there will be no added sewage, and thus no impact? CC-25

9. Consultant JPR indicated that its conclusion of no impact from sewage was based on its review and discussion with others. It further indicated that it did not do a review of public comment, but rather relied on a information of others, including a telephone conversation with Dr. CP Gerba. Dr. Gerba opined that as far as community and hospital were concerned, the issue was one of the community at large rather than any individual contributor being a major foci. He went on to opine that there was nothing unusual about a hospital as compared with the community with regard to the discharge of pathogens to the sewer or the disposal of unused medicines. Based on this information, consultant JPR concludes that the issues arising from the community out weigh that of contributions from the hospital. The volumes of literature (which were presented, yet ignored by the DEIR) do not support either the conclusions of JPR or Dr. Gerba. Nonetheless, these conclusions form part of the basis upon which the DEIR depends for its less-than-significant stance as far as the sewer issues are concerned. Please explain how, in the face of this large body of literature, the DEIR came to such conclusions and how ignoring such data (which will be found again below) could the DEIR constitute a full disclosure document. What was the legal, let alone ethical, basis for failing to report this body of data as provided during the scoping session and at public hearing on October 30, 2003? CC-26

10. The DEIR discusses construction impacts on the sewer. It indicates that much of the impact could be obviated by the use of portapotties. These would be chemical toilets supplied to the workers, and then trucked away and pumped at the sewer plant. This "reduction" of impact is not a reduction at all but an unavoidable increase in adverse impact. These chemicals CC-27

disrupt the biological system upon which sewer works depend. Further, the chemicals affect environmental systems beyond the plant. Staff at the sewer plant indicate that dumping this material is no longer allowed for the above reasons. Thus this waste is now shipped elsewhere for disposal. Nonetheless, this is merely pushing it into the back yard of someone else, hence an off-site cumulative impact. This also indicates that not much thought went into this alternative mitigation for the sewage issue. Again this points to the fact that those evaluating this area have little understanding of its critical impacts. Yet these people feel comfortable making comments and conclusions upon which busy decision makers, themselves not expert, must depend to protect the public health, the environment and honor the public trust.

CC-27

CONSTRUCTION OF THIS SUBMITTAL

How is this submittal is constructed? I have assembled several types of documents from readily available published, peer reviewed scientific and medical literature. In some cases, I have reproduced either full text or abstracts. In other cases, I cite the literature. In any event, the data are readily available and have been so for decades. I am also resubmitting some of the original material sent directly to Cottage, the City, or regulatory agencies. This will include scoping comments submitted by myself and Surfrider, and include comments on sewage, sewer works and issues of failure, antimicrobial resistance, carpeting as a source of pathogens, water resources and air resources as such relate to terrorism and weapons of mass destruction.

There are also works on standards from hospitals in other developed nations that discuss sewage issues. Additionally, there is a series on potential mechanisms and processes to deal with issues that I have raised.

Again, let me say that my aim here is to assure that there is a full disclosure of issues and options. This will hopefully allow decision-makers and the public to assure a transparent system, a full disclosure document, empowering the finest project within human ingenuity.

I will attempt to use a 3-level system of analysis here: Issue; Evidence; Their argument/Our response. Since, it is difficult to put in 3 columns. I will generally use 3 levels as follows:

1. Issue
2. Evidence
3. Argument

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ISSUE

Both the EIR and the Initial Study/Environmental Checklist conclude that there will be no adverse or significant impact accruing to Cottage Hospital's sewage discharge. Part of this argument can be augmented by the absence of analysis on Goleta Valley Hospital (GVH), especially per Alternative to the Project 4B. The absence of adequate analysis of GVH thus skews the data on Cottage relating to actual bed utilization as well as sewage issues. Further, it impacts issues of security, especially if GVH is closed post completion of the Cottage Project improvements, thus leaving Cottage as the sole monopoly source of hospital health care.

EVIDENCE

The EIR @ p. 1-75, under POTENTIAL ENVIRONMENTAL EFFECT, CLASS III IMPACTS: LESS THAN SIGNIFUICANT, subcategory HAZARDOUS MATERIALS, indicates the following.

Project Long-Term Sewage Impacts. ***"Potential sewage hazard impacts are not anticipated with the proposed project or Specific Plan build-out. The amount of sewage generated would decrease at full bed occupancy compared to the existing condition. Therefore, it is anticipated that the amount of "potentially hazardous" human waste generated would be less than the existing condition."*** CC-28

The analysis of Cumulative Long-Term Sewage Hazard Impacts argument also uses the above logic (see p. 1-75).

The "During Construction Sewage Hazard Impacts" discussed immediately below are also calculated to be of less than significant (see also p. 1-75). The EIR stresses that portable potties can be used by construction-workers, then pumped into vacuum trucks for disposal into the sewer plant. Here they also error. The dumping of portable sewage fluids into the El Estero treatment works by Marborg has shown to drastically upset and alter the capacity of the treatment works. This is well known and thus is no longer allowed. The DEIR consultants were presumed to have discussed the issues of Cottage sewage with staff at the treatment works. It is obvious from this that somewhere with in the analysis, if in fact city sewer staff even looked at the DEIR and its data they were less than

forthcoming. Marborg and others must now haul this type of portable potty waste to another treatment plant. This impact on other treatment plants, if the material even goes to such works, thus needs review within the EIR, especially if the alternative site processing is disrupted and untreated outfall is allowed to go to the ocean. This then becomes a cumulative adverse impact that is not currently avoidable, let alone discussed within the DEIR and thus no mitigation is given.

CC-28

ARGUMENTS

THE SEWER EFFLUENT VOLUME (QUANTITY) ISSUE

Thus let's start with just sewage volume (quantity), I will get into the quality issue with resistant pathogens, pharmaceuticals, therapeutic materials, and disinfectants presently. One of the issues that would easily allow interjection of this issue of "volume" as a valid argument would be in their discussions of alternatives to the project, especially Alternative 4B, as found on p.15-26. In this one case the EIR uses an expansion of Goleta Valley Hospital (GVH) as part of an alternative to the Project. At p. 15-11, they note, speaking of Cottage itself, but this logic should also accrue to GVH----,

"Retrofitting the hospital would only improve the seismic performance of the hospital temporarily. According to SB 1953, retrofitting must be conducted by 2008 and retrofitted hospitals would need to be replaced by 2030...and this does not meet the basic objective of providing long-term health services..."

CC-29

If the above logic also accrues to GVH, which it should, then unless completely rebuilt and not merely retrofitted GVH must close by 2030 and the patients must find alternatives. Here we may have a cumulative impact. On the other hand, if it is not retrofitted, it must close by 2008—prior to the time Cottage must be completed. Thus eventually, Cottage would receive GVH patients—unless GVH undergoes complete seismic refurbishment allowing operation beyond 2030. The EIR does not seem to discuss any of these potential events and thus is deficient, thereby misleading the decision-making process.

The EIR continues at p. 15-26, indicating that GVH is a 122-bed acute care facility with level IV trauma capability. Cottage wants to move up in its own trauma class and it may make questionable sense to maintain both of these level IV systems in close proximity and this seems not to have been discussed within the DEIR. Thus, one might argue that Cottage would close the level IV trauma center at GVH as it opened the one at Cottage. This would further depress GVH's patient load. This eventuality, either augmentation of Cottage's trauma level or diminution of GVH is also not discussed in the EIR, nor is the projected impact on patient base at either campus discussed.

CC-30

The EIR notes that an average of 12 people are hospitalized each day at GVH, filling less than 10% of its 122 beds (see p. 15-26, under Alternative # 4B). Thus, if I'm not reading this incorrectly, there are 110 vacant beds at GVH. This is verified at p. 15-33 wherein the EIR states that there are 110 empty beds/day at GVH.

Here we have a potential mixed and disfunctional logic within the DEIR. If the document can successfully argue that closing St Francis added minimally to the occupied bed count at the main campus in Santa Barbara and that with its low census at GVH as a transfer would also add minimally, then they are saying that full licensed bed count is a fiction. CC-31

This then puts them at crossed logic with respect to their argument that by reducing current licensed bed count of 456 to 337 thus is a valid way to say that sewage is reduced. On the other hand, their "licensed" bed count can be used to argue that eventual cessation of GVH would push them into yet higher sewage production.

GVH is, according to the EIR, currently under evaluation for seismic upgrading, but no more information is forthcoming on this situation. Thus the DEIR is deficient as the status of GVH is critical to the overall equation. This statement ("under evaluation"), while it keeps the door open on the subject, should be explored in more detail within the EIR process. Will GVH likely be upgraded? As mentioned above **if** GVH is not upgraded, it must close as an acute care hospital by 2008 and thus its patients transferred to Cottage. The EIR does not seem to consider this. If it is merely retrofitted then, there is a time limit (2030) for its operation. Again this is not discussed. The project "life" should also be clarified. How far into the future does the DEIR cover for impacts, including cumulative impacts. I don't think that horizon, although critical, is specified. Thus this needs to be explicit within the DEIR. CC-32

There is much in the DEIR that supports the closure of GVH. The DEIR at p. 15-32 and elsewhere, uses a statement from the newspaper The Beacon., This statement, which is used in the DEIR, is for purposes of augmenting arguments that are positive for the Cottage Project, but which can also be easily turned around to argue closure of GVH. The EIR indicates that ***"As current conditions show, acute care facilities at Goleta are not being utilized primarily because doctors want patients closer to their offices...."*** These offices, continues the DEIR, are in Santa Barbara near SBCH. Improving Goleta would require the construction of medical offices. (I comment here that the Cottage project will merely accentuate this asymmetrical issue and thus exacerbate the condition at GVH.)

At p. 15-26, under discussion of Alternative 4B, where GVH is theoretically expanded, and then this straw-man is discounted to supplement arguments for the Cottage Project, there would be improvement to GVH to supply 208 beds, CC-33

built on two floors, i.e., 104 beds per floor thus exceeding its existing limit of 122. This increase would thus impact sewage. Under the subsection on Hazards found at p. 15-28, there is no discussion on sewage impacts. Thus, the DEIR is deficient.

CC-33

The DEIR needs to include a full discussion of the hazards of sewage, especially with the treatment plant being at the Goleta Sanitation District, near the end of the Airport. Goleta San is currently arguing to maintain its ability to put out primary treated effluent. Its output is 40% primary and blended 60% secondary treatment. Thus, Goleta San is even less well equipped to deal with pathogens and pharmaceuticals than El Estero. Further, there is also the question of leaking sewer mains, blown-off sewer man-hole cover lids releasing raw sewage during storm events, thus mixing with storm water, and hence impacts to the nearby estuary and wildlife sanctuary, ultimately the beach and ocean. None of this is discussed.

This discussion within the EIR would not only need to analyze the issue of sewage and all its ancillary issues under Hazards, but also under the separate headings of Hydrology and Water Quality. These later issues would accrue to leaking sewer mains, blowing off of sewer man-hole covers and escaping sewage mixing with storm water and then estuary and ocean water quality issues as well as arguments from treatment plant failure, especially because of the Goleta San's current use of primary effluent release is less well treated. All this could also be brought in under laws discussing protection of the ocean, estuary, and coastal resources.

CC-34

Through these above issues being argued here, the sewer issues are brought out into the open so decision-makers and the public can see the potential impacts clearly. This also allows one to contrast this with arguments within the DEIR that the Cottage main project in Santa Barbara will not exceed current sewage flows.

This may not only accrue the displaced GVH patients and loss of the level IV trauma center. It will also happen with the proposed additional100 nursing beds as well as its reconfigured 337 beds at 70% occupancy (456 X 52% versus 337 X 70% giving essentially the same number of occupied beds), and projected added out patient volume of an additional 22,000---all will exceed current sewer flows; more even if GVH also closes its doors. In **either case**, there is a need to discuss the sewer issue and thus the impact of hospital sewage—a discussion that has been carefully kept out of the EIR. (see also areas where these issues can be discussed-- HYD @ p. 17-45, 17-54, and reprocessing bedpans and urinals daily @ p. 17-74)

CC-35

THE SEWER EFFLUENT **QUALITY** ISSUE

CC-36

In its submittal to the City's Initial Study and request for comments (RFC) of the scoping document, Surfrider supplied a litany of citations as well as reasoned arguments why the issue of hospital sewage was important, was more extensive than mere "less than significant" and thus suggested the need for a study. The overall thrust of such a study was also discussed in the Surfrider comments.

McGowan also submitted similar arguments and testified before the Planning Commission (PC) as an expert. Since the issue was argued from the point of McGowan being an expert that contrary to the Initial Study (IS) which noted sewage as a less than significant issue, sewage actually had a potentially significant and non-mitigable adverse impact, unless scientifically valid pretreatment studies were conducted and showed conclusively that there was no issue. Scientifically valid studies have not been conducted.

This argument for a scientifically valid study was accepted by the PC and it admonished City staff to utilize the expertise within the community to further develop these concepts. As noted within the current DEIR, neither the argument from an expert (McGowan, nor the admonition of the PC to look more deeply and use citizen resources were heeded). It was also stressed by McGowan that neither the city staff in planning nor sewer works were experts in communicable disease, infectious disease, or medical microbiology, especially with respect to drug resistant pathogens, movement of mobile genetic elements, the terra-accumulation of such within environmental niches and thus the reliance on them as expert would misguide the City's decision-makers, the PC and also the EIR, hence the public interest.

CC-36

Additionally, McGowan had composed a letter to members of the City's sewer staff at El Estero carefully outlining the various issues and arguments, including abundant citations as to why this was a critical issue. In spite of this letter with its citations, the City still seems to either continue to be uninformed or flatly refuses to acknowledge the issue. The City continues to claim that there is no problem.

Hospital effluent is not the same as urban effluent. In furtherance of the quality issue, one need merely look at papers in the published peer-reviewed literature. I will mention two here, although within the submitted data, there is a raft of these that have been copied for staff to review. Some go back into the early 1970s---thus this information is neither startlingly new nor obscure.

The first is that of Vikrant Chitnis, et al, entitled ***Hospital effluent: A source of multiple drug-resistant bacteria***, published in Current Science October 2000. This publication date puts it well within the literature base that was available to the peer review for the EIR and its preparation staff. The abstract is noted below. It is important here to look at the numbers. If one does the math, i.e., by dividing the worst case level of hospital resistance (40%, by the best case of the urban, i.e., 0,00002%, as the worst possible but nonetheless studied case), one notes a 2,000,000 fold difference between hospital effluent and urban effluent.

This difference between hospital and urban (in this case a difference of 2,000,000) is what I mean by a **quality** difference. Thus, the volume of sewage, i.e., the quantity, must be reduced by some major amount for the risk from hospital effluent to fall and thus be equal that represented by the community. This then should obviate the argument that merely reducing the licensed bed count is a valid method to skirt around this issue. These papers also refute the statement, as used by JPR, that there is no difference between hospital effluent and that derived from the community. This argument, that there is no difference, is also championed by the city staff. In either case, the literature clearly shows a difference. Ignoring such difference would be foolhardy.

CC-36

Below is the abstract. If one had read the literature, per a peer review, one would also note that K Brown of New Mexico in her study of the Rio Grande River around Albuquerque also came to the same conclusions as Chitnis. Additionally, both Surfrider and McGowan cited studies that demonstrated a difference in effluent quality between hospital and urban effluents---unfortunately, this material, as noted by JPR, (see Vol II of EIR @ Appendix F, Review of Public Comments Regarding Hazardous Waste—Peer Review of Site Mitigation Plan—Central Plant Improvement Project, p. 1 et seq.) was not used.

As stated by the consultant JPR within this Peer Review section, it was not a "peer review". The JPR author clearly states and is very up front, in the second paragraph of the opening statement---***"It is important to note that the review conducted by JPR was NOT a 'peer review'...."*** (My emphasis added). The paragraph then goes on to state that only selected documents from other sources were used to come to the **conclusions**, as well as interviews from the city staff, Cottage, and a phone conversation with Chuck Gerba @ Arizona. It will be noted below via Chitnis, Brown and others, that conclusions from Gerba, hence the DEIR are wrong.

Further, in the closing statements of this JPR "peer review", its author indicated that, based on the **conclusion,** which was obtained by the use selected documents and other selected sources, but not the material submitted by comment, the project would result in a less than significant impact.

CC-37

However, the JPR author goes on to cover this **"conclusion"** by the caveat indicating that ***"a third party with advanced expertise in the study of environmental microbiology be retained to conduct a technical analysis of the public comments...."*** In short, it appears that a "cooked" analysis, masquerading as a peer review has been used to bolster the **conclusions** carried within the body of the DEIR and initial study, indicating that there is no impact from sewage. In the latter case there was ample time to review the citations found within material submitted by public comment. It appears that in spite of being directed by the PC to carefully evaluate this material, the City and DEIR writers ignored the body of such material. Thus in either case DEIR or

Initial Study, an incomplete analysis of information lead to a potentially preconceived conclusion previously put forward carefully skirting the issue of hospital effluent as well as failure of sewer works.

CC-37

Nonetheless, using current scientifically valid and elsewhere peer reviewed studies, whether one argues from the perspective of quantity (volume of sewage), or its quality, the conclusion that there is less than a significant impact and thus no discussion is warranted appears to fail.

ABSTRACT from Chitnis, et al.

The present work was carried out to study the spread of multiple drug-resistant (MDR) bacteria from hospital effluent to the municipal sewage system. The MDR bacteria population in hospital effluents ranged from 0.58 to 40% for ten hospitals studied while it was less than 0.00002 to 0.025% for 11 sewage samples from the residential areas. Further, the MDR bacteria carried simultaneous resistance for most of the commonly used antibiotics and obviously the spread of such MDR bacteria to the community is an utter and grave concern.

Pathways to the environment and hence to man for drug resistance from hospital effluent have been discussed in several papers cited by both Surfrider and McGowan.

Contrary to popular myth, many pathogens survive their passage through a sewer treatment plant thus, remaining to constitute an increased public health risk. Gerba himself has several works published on this, see citations list below and also in attached copied data. These introduced pathogens as well as associated soil and water bacteria that can take on the genetic information, including viruses and other organisms, and act as lending libraries within the environment. The natural and vast reproductive potential of these organisms then allows for terrestrial and aquatic spread of this genetic information, hence movement to man and risk to public health.

CC-38

To give you some idea of the importance of this risk, the World Health Organization has raised the issue of antibiotic resistance to a Global Crisis. To further amplify this thought, below is a paraphrased statement by the WHO's chief of Communicable Disease, David Heymann, before the US Senate hearing on The Spread of Communicable Disease, in 2001.

Some microbes have accumulated resistant genes to virtually all currently available drugs. Thus, these have the potential to cause untreatable infections. Accordingly, such diseases may have no effective cures over the next 10 years unless there is some uncharacteristic breakthrough in drug therapy. Therefore, if current trends continue, many important medical and surgical procedures, including cancer therapy, bone marrow

and organ transplant, hip and knee replacement, and perhaps coronary bypass surgery could no longer be undertaken without undue risk of unstoppable infection.

In spite of such warnings, it appears that the City and its decision-makers are unfortunately ignorant of such. The tragedy is that this amounts to a risky behavior that could impact the community's health. That this situation has continued for some time may be attributed, in part, to politics---not science—and economics as well as the antiquated water quality standards.

The City on its own is capable of exceeding current standards for the protection of its citizens. It appears that it has chosen to ignore the situation for political and short-term economic issues. Nonetheless, readily available scientific and medical literature are, and have been for some time, replete with data demonstrating and confirming this fact that current standards are inadequate. An ample data-base discussing failure of current standards was submitted in public comment by Surfrider, McGowan and others. This is also reflected in Gerba's work, see citations below as well as copied and submitted documents. Yet, the City and the DEIR consultants seem to have chosen to ignore such material.

The logic in standards using indicator bacteria, is that bacteria: a) provide accuracy in measure and the density of serious pathogens, and b) that the demonstration of reduced bacterial density is sufficient to guarantee that pathogenicity is adequately controlled. **In both of these cases, neither assumption is accurate, as demonstrated by volumes of literature. Again, little of this has been discussed, certainly not adequately, within the DEIR.** CC-38

Studies reported in the scientific and medical literature dating back to at least the 1970s show failure of treatment and standards. Thus, this is hardly new knowledge, nonetheless, the DEIR ignores this information, misguides decision-makers and consequently increases the chance for adverse risks to public health. [Fontaine, et al, (1976); Grabow, et al. , (1973); Linton, et al., (1974); Walter et al,. (1985), Gerba, et al., (1993)].

It was assumed for a long time that gene transfer between different species of microorganisms is a very rare event at best. That view has changed. The available evidence suggests that interspecific transfer of genes has occurred between the three major groups of organisms: archaebacteria, eubacteria and eukaryotes. There is very strong evidence that gene transfer easily occurs between distantly related bacteria. Marcinek, et al (1998) [10] estimated that under the natural conditions of a sewer treatment works, between 10^{6} to 10^{9} gene transfer events between different *E. faecalis* strains should take place per day. The maximum number of transfer events for the sex pheromone plasmids between different strains of *E. faecalis* in the municipal sewage water treatment plant was found to range from 10^{5} to 10^{8} events per 4 hour period. This work

also indicated that gene transfer should take place under natural conditions following release of sewer effluent.

Iversen, et al, (2002) [11] isolated VRE in 21 of 35 untreated sewage samples (60%), from 5 of 14 hospital sewage samples (36%), from 6 of 32 treated sewage samples (19%), and from 1 of 37 surface water samples. It was speculated that antimicrobial drugs or chemicals released into the sewage system sustained VRE in the system. Others [5] have demonstrated direct evidence that related tetracycline resistance-encoding plasmids have disseminated between different *Aeromonas spp.* and *E. coli* and between the human and aquatic environments in distinct geographical locations. Collectively, these findings provide evidence to support the hypothesis that the aquatic and human compartments of the environment behave as a single interactive niche.

CC-38

Ribeiro (1983) [12] and others [13] (see Nakamura S, et al [1990]) have found that as these organisms progress further through sewer treatment, the level of resistance and number of transferred plasmids increases. Reinthaler et al (2003) [14] found that the highest resistance rates were found in E. coli strains of a sewage treatment plant which treats not only municipal sewage but also sewage from a hospital. Thus, these authors concluded that sewage treatment processes contribute to the dissemination of resistant bacteria in the environment.

Here we enter the argument, also not discussed within the DEIR, that multiplication from seeded material supplied by hospital effluent leads to spread of both resistance and virulence within the sewer plant by mixing during wastewater processing and also after its release, thence into the environment. Thus, here we have another **quality** issue that may be independent of arguments on quantity or volume.

The transfer of genetic information between previously separated pathogens is facilitated once they are within the common melting-pot or soup of a sewer treatment works. Looking at the rate of reproductive turnover of some microorganisms, even a few seeded pathogens or other organisms holding high level virulence or high-level multi-resistance and then transferring the necessary genetic information, allows for astonishingly large numbers to be duplicated in short periods of time. This is also augmented by other materials coming from hospitals that augment and select for resistance.

CC-39

We have previously raised the question on capacity of sewer works to actually contain and then clear pathogens before their release to the environment as either wastewater out-fall to the ocean or rivers, or as condensed sludge sent to products such as potting soils, or used on farms. Gerba and Pepper have produced papers discussing the dangers of pathogens both within sewer sludge, their survival and movement from applied sludge to environmental niches. The survival of viable infective pathogens is astonishingly long-standing. In one paper Gerba describes pathogen survival from sewer effluent in the near marine

environment and estuary mud not in days, weeks, or months, but rather for 13.4 years---all subject to re-entrainment and movement with resuspension of that mud.

CC-39

Here then we get into some off-site and cumulative impacts from the discharge from Cottage. It is known that the sewer man-hole cover near Marina #3, which is down-gradient from Cottage, blows off during storm events. This releases raw sewage to the harbor area. Considering the long-term survival of pathogens within marine mud, especially from highly polluted sources (Gerba citations) and that this survival allows for continued health risk (Gerba) and additionally that this pathogen laden material is easily transported (Gerba)---or moved by dredge, one might conjecture that East Beach may be contaminated by Cottage effluent via dredge spoilings being thus pumped there.

Of potting soils made from composted sewer sludge, the literature discusses the passage of Legionella, hence Legionaire's disease, a respiratory disease of high mortality, to the innocent purchasers of potting soils. The use of sewer sludge, and its land application,-- begs the question of dust drift and thus the public health impacts. There are excellent studies by the USGS which demonstrate that pathogen-laden dust arising from West Africa is carried to the upper atmosphere where it is subjected to intense ultra violet radiation, lofts over the Atlantic, to fall out 2 to 3 weeks later over the Caribbean, thus causing respiratory disease. These are the same basic transport mechanisms that affect movement of agricultural soils, hence dust into adjacent neighborhoods. There are papers by Gerba and Pepper discussing the fact that pathogens are found in sewer sludge and other papers by these same authors indicating that dust on every-day items may contain pathogens and that merely touching every-day contaminated items can result in a sufficient dose of pathogen to initiate disease. Thus, those exposed to deposits of dust drifting from agriculturally applied sludge may find themselves at higher risk, an externality of land applied sewer sludge. This would be an off-site cumulative impact from effluent derived from Cottage. Rusin & Gerba produced a paper (seen within this comment document) demonstrating surface to hand, finger to mouth of sufficient quantities of pathogens to promote disease.

CC-40

This failure within the DEIR to discuss off-site pathogen movement through land application of sewer sludge also neglects any discussion of transfer of resistance and virulence to background soil and water microbes, not all such microbes need to be confined to the classes of bacteria. Gerba and others have papers discussing movements of viruses into soils, their survival, movement off site of application and potentially into ground water.

As these transferred mobile genetic elements (MGEs) are moved into air streams or water-courses, they eventually add to the terra-accumulation of resistance. As demonstrated within the cited papers and cited documents submitted as comments to the city and this DEIR process, but not peer reviewed, there are

several papers leading to discussions on examples where MGEs and genetic material was transferred to non-pathogens which then acted as lending libraries for this genetic information.

Dr. Stuart Levy in his famous book, ***The Antibiotic Paradox***, gives several examples of the transfer of antibiotic resistance from and through various sources to man, even though those affected took no antibiotics.

CC-40

COTTAGE BED COUNT ISSUES.

ISSUE

Cottage claims that its reduction of licensed beds down to 337 from 456 obviates issues of sewer water.

EVIDENCE

Within the DEIR @ p. 1-75, discussing the long-term impacts of sewage, the conclusion is drawn that because of the reduction of licensed beds from 456 down to 337, there must accrue a reduction of sewage—hence no impact. This argument is also used to nullify the cumulative impact as well as construction related impact.

ARGUMENTS

Let's examine these figures. First, per the DEIR, much of this argument is affected by the numbers and terms used by Cottage and the City. There seems to be some inconsistencies in these. To elaborate on this last idea, one finds occupied beds, not licensed beds determine an important parameter in actual water usage, hence wastewater. This is ignored within the DEIR and the argument put forward by the DEIR is reliant on a difference in pre-project and post-project licensed beds.

CC-41

Nonetheless, the DEIR carries various and differences in its average occupied baseline and then projected numbers of occupied beds. These numbers range from 213 to 248.

The basis of the argument put forward by Cottage and the City is that the quantity (volume) of effluent will diminish because of the reduced number of licensed beds.

First, this ignores a critical consideration-- that of current census, not licensed beds as a baseline. It is thus critical for our case to successfully argue that occupied bed count and not licensed bed count is the determining factor here, at least to overcome the Volume portion (quantity) of the overall water

quantity/quality issue of sewer effluent. It is also critical that we successfully introduce this issue of duality, i.e., the quantity/quality issue.

Thus from that success one may use the two critical aspects needing consideration when one discusses any fluid, wastewater in this case. The first is quantity (volume), the other quality. Quality thus looks at concentration of constituents and their ability to effect some change. As an example, distilling off water leaves a more concentrated residue. If we put this into the context of a toxin, it will take much less of the concentrate to cause a toxic reaction than the previously diluted material. The inverse would be to add toxins and thus boost an adverse reaction. We may reduce the volume, but if over time we increase the toxicants have an different fluid. Cottage will be facing a dynamic situation where it will be releasing effluent with increasingly resistant pathogens, hence the this fluid will also contain materials needed to combat those pathogens, i.e., its released concentration will go up.

We have seen in the discussions above that per the Chitnis, et al paper, there was, in the worst case situation, a 2,000,000 fold increase in the quality aspect of sewage coming from hospitals compared to urban environments. Even with his example of the best case scenario, i.e., 0.58% hospital to 0.025% for urban community, this is a 23 fold increase, or flipped, there would need to be a 23 fold reduction to make the level of resistance equal to the urban effluent. There is currently no reduction in actual effluent discharge with Cottage. CC-41

Added to this is the work of K. Brown, the paper submitted to the Planning Commission on Dec 2, 2004, and the raft of papers found attached discussing Hospital Sewage.

Thus, we have excellent papers on point--lightning striking several times in the same spot. This is augmented by the citations within both papers as well as the citations submitted during scoping (but essentially ignored) within the materials of Surfrider and McGowan (see also attached). Together, this makes a strong argument for the quality side of the equation, none of which seems to have been peer reviewed for construction of the DEIR (see statement in DEIR Appendix F by JPR).

Additionally, from the quantity side of the equation the hospital indicates that it is proposing an added 100 bed nursing facility. Further, the DEIR indicates that transfer of the St. Francis patient load, although not all of it will now fall to Cottage. This they say will add the difference between 213 and 226, i.e., 13 estimated occupied beds. This is interesting since St Francis had 85 licensed beds, an average census of about 94, but as high as 128 (according to personal conversation with the former Nun administrator). Thus, there appears to be another factor here and that is a census outside of licensed capacity—a subject not discussed in the DEIR. Further, as discussed above, there is the issue involving GVH and its patient base.

Finally, there is an estimated added outpatient volume of 22,000 per annum, and the fact that Cottage is and has been proposing to become a higher-level trauma center. In the last case, Cottage claims that it is the regional center for the area between L.A. and San Francisco. Thus as a level-IV+ trauma center, one might expect it to be receiving trauma patients from the San Joaquin Valley and similar distant regions.

Based on the above, it appears that the level of wastewater effluent will increase not decrease. Nonetheless, the DEIR claims that the critical factor is the reduction of licensed beds from 456 down to 337. It would appear from the arguments put forth by Cottage and the DEIR, that these added people and staff will not be augmenting the sewer discharge. There is no compelling nor sound evidence for such an argument within the DEIR.

Accompanying this overall discussion, the DEIR (if one computes the numbers) mentions that current census runs somewhere variously between 48% to 53% of capacity. Thus, the calculation of 456 X 0.52 obtains 237 occupied beds on the average. The hospital predicts of the new level of licensed beds, 337, 70 % will be occupied. This accrues to the fact that not all multi-bed rooms can be filled because of treatment protocols and gender differences and state regulations. Thus, the 337-bed system is more efficient for Cottage. Using the same math, 337 X 0.70 obtains 236.

CC-41

Thus, in reality, the census, absent any added nursing beds (100 beds) and outpatients, (22,000), as well as potential closure of GVH, and a more detailed analysis of the licensed beds at St. Francis, remains essentially the same, i.e., 236 or 237.

Accordingly, from an occupied bed count, the actual number is going up (100 nursing beds). One also needs to look at short-stay bed usage and its turnover to get a more accurate analysis. Part of the short stay will be found within the additional 22,000 out-patient number. The DEIR does not go into this. Short stay is and will become an increasing level of usage, again such impacts warrant consideration not now found within the DEIR.

None of this is material is accurately reflected within the DEIR. Further, discussion of such would then push for yet further analysis of impacts on water quality, hence marine, and terrestrial environmental resources as well as human health. Many of these issues may fall within the cumulative area of off site impacts, yet the DEIR is silent. Certainly more discussion is warranted for this to be a full disclosure document. By neglecting to discuss the above, the document misguides both the public and its elected representatives.